

Our Ref. No.: 37231.P004

UNITED STATES PATENT AND TRADEMARK OFFICE

Larry Hood, et al.

Serial No.: 08/111,296

In re the Application of:

Filed: August 23, 1993

For: METHOD FOR MODIFICATIONS

OF VISUAL ACUITY BY

THERMAL MEANS

Examiner:

Art Unit: 2507

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Honorable Commissioner of Patents and Trademarks Washington, DC 20231

Applicant would like to disclose the following patents pursuant to his duty of candor and good faith under 37 C.F.R. § 1.56. The cited art is listed below and on Form 1449 which is attached, copies of the art are enclosed.

U.S. PATENT NO.	PATENTEE	ISSUE DATE
3,776,230	Neefe	December 47 1973
4,326,529	Doss, et al.	April 27, 21982
4,381,007	Doss	April 26, 1983
4,461,294	Baron	July 24, 1984
4,729,372	L'Esperance, Jr.	March 8, 1988
4,747,820	Hornlein, et al.	May 31, 1988
4,798,204	L'Esperance, Jr.	January 17, 1989
4,931,047	Broadwin, et al.	June 5, 1990
4,976,709	Sand	December 11, 1990
4,988,334	Hornlein, et al.	January 29, 1991
5,015,227	Broadwin, et al.	May 14, 1991
5,025,811	Dobrogowski, et al.	June 25, 1991

5,137,530	Sand	August 11, 1992
5,174,304	Latina, et al.	December 29, 1992
5,188,125	Kilmer, et al.	February 23, 1993
5,190,517	Zieve, et al.	March 2, 1993
5,195,954	Schnepp-Pesch, et al.	March 23, 1993

## FOREIGN PATENT DOCUMENTS

PATENT NO.	PATENTEE	ISSUE DATE
WO90/12618	Spears, et al.	November 1, 1990

## OTHER DOCUMENTS

"An Electrothermal Technique for the Alteration of Corneal Curvature," Doss, et al., Los Alamos Scientific Lab, February, 1978.

"A Technique for the Selective Heating of Corneal Stroma," Doss, et al., Contact & Intraoccular Lens Medical Jrl., Vol. 6, No. 1, January-March, 1980, pps. 13-17.

"Bipokeratoplasty: using cautery to advantage," Fugo, Ocular Surgery News, February 1993, pps. 101 & 113.

"Combined Microwave Heating and Surface Cooling of the Cornea," Trembly, et al., IEEE Transactions On Biomedical Engineering, Vol. 38, No.1, January, 1991, pps. 85-91.

"Regression of Effect Following Radial Thermokeratoplasty

"Regression of Effect Following Radial Thermokeratoplasty in Humans," Feldman, et al., Refractive and Corneal Surgery, Vol. 5, September/October, 1989, pps. 288-291.

"The Need For Prompt Prospective Investigation," McDonnell, Refractive & Corneal Surgery, Vol. 5, January/February, 1989.

The applicant will discuss the references in more detail below.

U.S. Patent No. 4,461,294 issued to Baron; U.S. Patent No. 4,976,209 issued to Sand; U.S. Patent Nos. 4,326,529 and 4,381,007 issued to Doss are discussed in the Background of the above entitled application.

The Trembley reference discusses a microwave procedure similar to the technique disclosed in the Doss patents.

The Fugo reference discloses a Bipokeratoplasty technique applied to the limbus of the cornea.

The Doss article discusses a procedure wherein the circulating saline electrode (CSE) of the Doss patent was used to heat a pig cornea. The electrode provided 30 volts r.m.s. of power for 4 seconds. The results showed that the stroma was heated

to  $70^{\circ}\text{C}$  and the Bowman's membrane was heated  $45^{\circ}\text{C}$ , a temperature below the  $50\text{-}55^{\circ}\text{C}$  required to shrink the cornea without regression.

The McDonnell reference discusses the merits of corneal reshaping by thermokeratoplasty techniques. The article discusses a procedure wherein a stromal collagen was heated by radio frequency waves to correct for a keratoconus condition. As the article reports, the patient had an initial profound flattening of the eye followed by significant regression within weeks of the procedure.

The Feldman reference discusses another thermokeratoplasty technique for correcting hyperopia. Feldman inserted a probe into four different locations of the cornea. The probe was heated to 600°C and was inserted into the cornea for 0.3 seconds. Like the procedure discussed in the McDonnell article, the Feldman technique initially reduced hyperopia, but the patients had a significant regression within 9 months of the procedure.

The remaining art is of general interest. The applicant submits that the above cited art neither anticipates nor renders obvious the present invention.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN

Ben yoda

February 17, 1994

BEN YORKS Reg. No. 33,609

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12400 Wilshire Boulevard, Seventh Floor . Los Angeles, California 90025 (310) 207-3800 I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C.

Cheryl Plunkett February 17, 1994